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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,520	01/17/2002	Qing Qi	CS13-PT001	6223
3624	7590	04/12/2004	EXAMINER	
VOLPE AND KOENIG, P.C. UNITED PLAZA, SUITE 1600 30 SOUTH 17TH STREET PHILADELPHIA, PA 19103			PRATS, FRANCISCO CHANDLER	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 04/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/031,520

**Applicant(s)**

QI ET AL.

**Examiner**

Francisco C Prats

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-15,17-22,24-29,31-36,38-43,45-50 and 52-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-15,17-22,24-29,31-36,38-43,45-50 and 52-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                                                 |                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                            | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11-26-2003</u> . | 6) <input type="checkbox"/> Other: _____                                                |

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**DETAILED ACTION**

The amendment filed March 4, 2004, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 1, 3-8, 10-15, 17-22, 24-29, 31-36, 38-43, 45-50 and 52-71 are pending and are examined on the merits.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to

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point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1, 3-6, 8, 10-13, 15, 17-20, 22, 24-27, 29, 31-34, 36, 38-41, 43, 45-48, 57-61 and 63-71 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Shinpo et al (JP 58-128322) (translation supplied herewith).

Shinpo discloses a glycoprotein having anti-cancer properties which can be prepared from Spirulina. See, e.g., translation at page 2, claims section. The prior art glycoprotein is disclosed at pages 3 and 4 as being prepared by a process comprising the steps of:

- dispersing 500 g powdered algal bodies in 5 L water (a 1:10 ratio),
- performing a hot water extraction at 95 to 100°C for 20 to 30 minutes,
- centrifuging the hot water extract and obtaining the supernatant,
- cooling the supernatant to 50°C and concentrating the solution under reduced pressure,

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- filtering the extract through a semipermeable membrane,
- subjecting the filtrate to chromatography, and
- freeze drying the resulting product.

The prior art product appears to be identical to the presently claimed product, based on the fact that the prior art product is made by a process essentially the same as recited in applicant's product-by-process claims -- hot water extraction of dried *Spirulina* cells including a dispersing (i.e. stirring step), followed by extraction under essentially neutral conditions, followed by drying. Note specifically that the prior art product is described as a "glycoprotein" which describes the same product as the claimed "proteoglycan." Note further that the reference discloses that weak acid or alkali may be used in the initial extraction step. See page 3 of translation. ("The medium used in [the] above extraction is not limited to hot water; there are no impediments to using water with a weak acid or alkali."). Note still further that the product recited in applicant's broadest claims encompasses a product produced by a simple hot water extraction because adjusting the pH to below 7 encompasses adjusting the pH to a value only nominally lower than pH 7.

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Thus, the proteoglycan product resulting from a hot water extraction followed by extraction at pH 6.999 followed by neutralization to pH 7 would not be any different than the glycoprotein produced by the hot water extraction of Shinpo. Consequently, the claimed product appears to be anticipated by the reference.

However, even if the reference product and the claimed product are not one and the same and there is, in fact, no anticipation, the reference product would, nevertheless, have rendered the claimed strain obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that the reference discloses the desirability of using the claimed steps to make a product having the claimed therapeutic properties, any nominal difference between the claimed product and the prior art product being expected differences between batches and or differences occurring due to nominal or optimized variations in the process steps. Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the propriety of this type of alternative rejection, note that MPEP § 2113 states that:

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. . . [w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972).

MPEP § 2113 also clearly states that

'The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature' than when a product is claimed in the conventional fashion. *In re Fessmann*, 180 USPQ 324 (CCPA 1974)."

### ***Claim Rejections - 35 USC § 103***

Claims 1, 7, 8, 14, 15, 21, 22, 28, 29, 35, 36, 42, 43, 49 50, 52-57 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinpo et al (JP 58-128322) (translation supplied herewith).

As discussed above, Shinpo et al disclose a glycoprotein having anti-cancer properties which can be prepared from Spirulina. As also discussed above, The prior art glycoprotein is disclosed at pages 3 and 4 as being prepared by a process comprising the steps of:

- dispersing 500 g powdered algal bodies in 5 L water (a 1:10 ratio),

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- performing a hot water extraction at 95 to 100°C for 20 to 30 minutes,
- centrifuging the hot water extract and obtaining the supernatant,
- cooling the supernatant to 50°C and concentrating the solution under reduced pressure,
- filtering the extract through a semipermeable membrane,
- subjecting the filtrate to chromatography, and
- freeze drying the resulting product.

Thus, the product-by-process claims and the process claims differ from Shinpo in not disclosing the step of adjusting the pH to 3.8-4.2 as recited in claims 7, 14, 21, 28, 35, 42, 49, 56 and 62. However, as also discussed above, Shinpo discloses that weak acid or alkali may be used in the initial extraction step. See page 3 of translation. ("The medium used in [the] above extraction is not limited to hot water; there are no impediments to using water with a weak acid or alkali.") The artisan of ordinary skill clearly would have recognized that performing extractions at different pH values would affect the properties of the resulting product. Thus, recognizing that extraction pH was a result-effective parameter, the artisan of ordinary skill



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clearly would have been motivated to have optimized that parameter to have produced a *Spirulina* hot water extract having maximal therapeutic efficacy. Therefore, the determination of a suitable pH for the acidic extraction of *Spirulina* according to the methods of Shinpo clearly must be considered an obvious optimization of Shinpo's process, and therefore unpatentable under § 103(a). Absent some demonstration of an unexpected result coming from the claimed extraction pH, a holding of *prima facie* obviousness must be maintained.

Lastly, as to the claims' requirement of a neutralizing step, note specifically that after initial extraction, Shinpo discloses bringing the extract to a volume of 1 L using distilled water, prior to subsequent purification steps. See sentence spanning pages 3 and 4 of the translation. While it is not clear that the solution was neutralized precisely to pH 7, one of ordinary skill clearly would have been motivated by this disclosure in Shinpo to have neutralized the solution. A holding of obviousness over the cited claims is clearly required.

### ***Response to Arguments***

All of applicant's argument has been fully considered with respect to the pending grounds of rejection, but is not

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persuasive of error. Contrary to applicant's argument, the product made by Shinpo is explicitly disclosed as being a "glycoprotein." The claims are directed to "proteoglycans," which language encompasses the same subject matter as disclosed in the prior art. In view of the fact that the prior art product is made from the same starting material as claimed, using the same process steps as claimed, it is proper to assume, absence evidence to the contrary, that the claims encompass the prior art product. Note that, as discussed above, applicant bears the burden of demonstrating a difference between the claims and prior art in product-by-process claims.

As to the failure of the prior art to disclose the claimed utilities (other than anticancer activity), the claims merely make a recitation of the intended use of the product. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant case applicant

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has not demonstrated that Shinpo's product is any different than that claimed, or that Shinpo's product lacks the utility recited in the claims. Note specifically that discovery of a new use for an old product does not entitle one to claims directed to the old product.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)



Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP